“Are We Missing Something?”

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A lot of the discussion in our section and the AAP as a whole is focused on how we can better relate to industry. We depend on medical manufacturers of pharmaceuticals and devices to provide us with what we need to treat our patients. Nevertheless, there is a fine line between what we can do with industry and how best to collaborate. To avoid the perception of conflict, we must identify, manage, and eliminate those relations that may, in some way, infuse academic content with commercial bias. However, there are other aspects of industry that we would be wise to study, to adapt to our needs, and to implement in order to develop efficient practices that eliminate waste, decrease cost, and streamline operations.

Following the second world war, Japan was in a shamble. With the efforts of Deming and others, Japan embarked on the creation of the foundation of what was to become Toyota Production System (TPS) or what many know as the Lean Manufacturing System. Lean programs have been implemented in many different industries and have been responsible for quantum changes in productivity. A new TPS system development, Toyota New Global Architecture (TGNA), offers the promise of additional gain in manufacturing prowess.

TGNA offers the promise of revolutionary change in the existing industrial environment. The new approach has the potential for producing an improvement in quality. Key changes must be implemented for this approach to reach its desired intent.

In essence, this system is about placing "more emphasis on harmonizing planning and design to increase efficiency." Although there is evidence that the goal is to create more standardization, aspects of Total Quality Management (TQM) are clearly present. Kaizen (改善, constant good change), Atariame Hinshitsu (当たり前品質, things are supposed to work the way they are designed), Kansei Kougaku (感性工学, a sensitivity or understanding present in engineering), and Miryokuteki Hinshitsu (魅力的品質, things should have an aesthetic quality) are all clearly present. It is more reasonable to refer to this as an incremental or evolutionary change since TGNA has essential elements of TQM. Although standardization of parts across major product lines is a core competency of this strategy, this concept is not new but harkens back to the roots of industrialization.

This new approach does drive a change in improvement. Fewer parts across an industry mean fewer standards and more focus on those that remain. Because workers do not have to learn multiple systems, they can focus on ones that are now common or more important. Fewer competencies to maintain allows more time to focus on quality initiatives. Should we not model our pediatric quality measures on focusing on what we really do well?

Harmonizing and synchronizing planning and manufacturing are vital changes. These drive strategy and quality. As costs decrease to manufacture multiple lines of products, the quality will increase because more resources can be devoted to each system. Would this system, appropriately fashioned, revolutionize pediatric care?

In sum, TGNA, albeit not revolutionary, has the capacity to drive quality. Its success depends on the company’s willingness to change.
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We welcome contributions to the newsletter on any topic of interest to the pediatric community.

Please submit your idea or article to:
Chester J. Koh, MD, FACS, FAAP at cxkoh@texaschildrens.org
to recognize where systems can be harmonized, the manufacturing process simplified, and shared components used to make time for quality improvement (2-4). As practicing pediatricians, we would be wise to adapt as well.

References:

From the Editor's Desk

“An All-Time Record Year for New Drugs Approval by the FDA”

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Welcome to the Fall 2019 edition of the AAP SOATT newsletter! We hope that you're enjoying the Fall weather (we are in Houston after a typical long and hot summer)!!

In case you didn't see the news, 2018 saw an all-time record for new drugs approvals, as a further sign that a “new FDA” is the norm which is leading to novel drugs and devices becoming available for the benefit of patients including children https://www.forbes.com/sites/bernardmunos/2019/01/14/2018-new-drugs-approvals-an-all-time-record-and-a-watershed/#6f15478b332d

For this edition of the newsletter, we complete our descriptions of the current FDA-supported pediatric device consortia and their approach to pediatric device innovation. In the last edition, three of the consortia descriptions (PPDC, SWPDC, and UCSF / Stanford) were highlighted, and the other two (NCC-PDI and West Coast CTIP) are included in this edition.

Drs. Animesh Tandon and Sarah D de Ferranti provide a Frame of Reference Perspective on Wearable Biosensors in Pediatric Cardiovascular Disease, and Dr. Therese L. Canares wrote a (Virtual) Reality Check: The Growth of Virtual Reality for Pediatrics, while Amy Ohmer, the director of the International Children's Advisory Network (ICAN), provides a preview of next summer's Summit in Lyon, France which will bring children together from all over the world to increase their voice and participation in clinical research.

The Pediatric Device Spotlight section describes the development and commercialization of new pediatric medical devices and hopefully serves as a resource and inspiration. This edition highlights the LifeBubble™ Umbilical Catheter Protection and Stabilization Device from Novanate

We'll see you soon at the 2019 AAP NCE meeting in New Orleans, LA (October 25 - 29, 2019). Be sure to attend the Section's activity including the Educational program on Pediatric Innovation on Monday, October 28.

We hope that you enjoy reading this edition of the newsletter, and please share it with a colleague, patient, or friend. We welcome all suggestions for articles, and especially those related to innovations in therapeutics and technology. It is an avenue of communication for our Section, and for those who share the passion of caring for children and improving our care for children.
Pediatric Medical Device Resource List:

FDA-funded Pediatric Device Consortia (PDC) – a resource for pediatricians, pediatric caregivers, pediatric specialists, engineers, and entrepreneurs in developing their innovative pediatric medical device projects. Available assistance can include consulting, project management, and seed funding.

Further details can be found in the previous editions of the newsletter on the Section website: https://services.aap.org/en/community/aap-sections/advances-in-therapeutics-and-technology/

FDA Pediatric Device Consortia Grants Program
(Office of Orphan Products Development)
https://www.fda.gov/industry/developing-products-rare-diseases-conditions/pediatric-device-consortia-grants-program

National Capital Consortium for Pediatric Device Innovation
(Children's National Health System / University of Maryland)
innovate4kids.org

Pennsylvania Pediatric Medical Device Consortium
(Children's Hospital of Philadelphia / University of Pennsylvania / Drexel University / University of Pittsburgh)
ppdc.research.chop.edu

Southwest National Pediatric Device Consortium
(Texas Children's Hospital and Baylor College of Medicine / Texas A&M / Rice / Univ. of Houston / Fannin Innovation Studio)
SWPDC.org

West Coast Consortium for Technology and Innovation in Pediatrics
(Children's Hospital Los Angeles / University of Southern California)
www.westcoastctip.org

University of California San Francisco-Stanford Pediatric Device Consortium
(University of California San Francisco / Stanford University)
pediatricdeviceconsortium.org

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If you are interested in joining the Listserv, email [jburke@aap.org](mailto:jburke@aap.org)
**Introduction to The West Coast Consortium for Technology & Innovation in Pediatrics (CTIP)**

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CTIP, the pediatric medical device accelerator based at Children's Hospital Los Angeles (CHLA) and the University of Southern California (USC) engages clinicians, engineers, regulators, hospital administrators, patients and the business community in the process of assessment and development of technology. CTIP has a network of children's hospitals, academic institutions, accelerators and incubators across the West Coast to support the commercialization of pediatric medical devices. CTIP network members include the University of California, Los Angeles; Oregon Health & Science University; University of Southern California; University of California, San Diego; University of California, Berkeley; Seattle Children's Hospital; Cedars-Sinai Accelerator; LA BioMed; and Project Zygote.

As healthcare is transforming, pediatric medtech also faces new challenges and more than ever, medtech commercialization success requires a clear and consistent focus on delivering differentiated value. The bar for demonstrating differentiated clinical and economic value is rising and medtech entrepreneurs and companies are forced to rethink how they can effectively create products, a product portfolio and/or an IP portfolio that will meet the ever increasing set of expectations. To account for these new realities, the CTIP team created a formula for innovation and commercialization; these include developing a toolkit of methods for the Evaluation of Pediatric Medical Devices. CTIP’s unique evaluation process is one way to assess the company's product pipeline, team structure, go-to-market strategy and R&D efforts. De-risking the device during this evaluation process is an essential component; we work closely with the founders and consultants to apply risk management procedures to the design and manufacture of their pediatric medical device. CTIP’s evaluation process also includes: Communicating the potential market dynamics and encouraging entrepreneurs to add as much value to their products as possible. Evaluation questions include: What stage is the company at? What are their multi-assets? Where is the location of the risk(s)? How will the device evolve the current standard of care over time? What is the manufacturing plan and scalability plan?

In 2019, CTIP improved our communications and transparency and organized efforts focused on various audiences to help people understand ‘the why’. We created unique programming to assist founders with their commercial story; articulating how their medical device can not only improve patient outcomes but create value for each of the key stakeholders across the healthcare delivery continuum. CTIP pinpointed the various organizational implications across a few healthcare systems and targeted bottlenecks that could delay adoption and diffusion in a timely manner. We developed solutions for these bottlenecks. We connected with key stakeholders and decision makers to determine incentives, opportunities for meaningful engagement and best practices for medtech ‘productivity’. CTIP worked closely with the portfolio members to understand that very few medtech companies mature into large, independent players. For the most part, most companies are acquired or pursue licensing and acquisition opportunities. Further, the life cycle of pediatric medical devices is a continuous process of managing the existing business, introducing new products and shepherding the growth of shareholder value.

Since September 2018, CTIP has advanced 77 pediatric devices, 37 of those are based on the West Coast. All companies are at different stages: idea and/or concept, design and prototype, licensing negotiation and companies immersed in fundraising and deal flow. In 2019, the CTIP portfolio leveraged over $45M in funding to support the continued device development. Our 2020 strategic plan includes: Increase the number of medical devices with labeling for pediatric patients, curate data on the unmet needs for pediatric MedTech, advocate for pediatric devices and reduce the barriers to device development. CTIP’s will take advantage of the unique talent base in Los Angeles, grow the network of accessible, experienced engineers, business development experts and individuals that can open doors, provide insights into the market, and give advice. We will leverage the deep pool of funding, resources and relationships available and distinct to the West Coast. Many new partnerships were created in 2019. These include: County of Los Angeles, California, Grid110, ScaleLA, Backstage Capital, IBM, Wilson Sonsini Goodrich & Rosati and Google. CTIP will continue to connect with traditional medtech companies who have started investing directly into smaller medtech startups and focus on strengthening the strategic partnerships CTIP has built and maintained since 2011. As we gear up for another dynamic year, our leadership team will stay attuned to 2020 medtech trends, dynamic nature of software regulatory requirements, considerations regarding AI and machine learning and the unique challenges of large clinical datasets and privacy issues.
Introduction to National Capital Consortium for Pediatric Device Innovation (NCC-PDI)

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The National Capital Consortium for Pediatric Device Innovation (NCC-PDI) was initially established as a partnership between Children’s National Hospital’s Sheikh Zayed Institute for Pediatric Surgical Innovation and University of Maryland’s A. James Clark School of Engineering in 2013. Now, in its seventh year of operation, NCC-PDI expanded its membership to two accelerators, BioHealth Innovation and MedTech Innovator, and the medical device design firm, Archimedic.

NCC-PDI’s mission is to facilitate the development and commercialization of devices that are indicated for use in pediatric patients or that are intended to treat, diagnose, or cure diseases from which pediatric patients suffer. The Consortium has served as an accelerator to medical device innovators that intend to label their device for use, in the United States, in a pediatric population or subpopulation. The Food and Drug Administration’s report to Congress on “FY 2017 Premarket Approval of Pediatric Uses of Devices” indicates that over a 10-year period (2008-2017), only 24 percent of the total PMA and HDE approvals in each fiscal year have an indication which includes a pediatric population or subpopulation. The report also indicates that since FY2008, the largest number of such PMA and HDE approvals was in FY2017 (18). This represents a formidable progress. A closer look at the data, however, suggests that the majority of these approved devices are labeled for adolescents (12 years through 21 years of age) in addition to older adults. There still remains a significant unmet need for devices labeled for neonates (birth until 1 month of age), infants (1 month until 2 years of age), and children (2 years until 12 years of age).

In 2015, we published a viewpoint in JAMA Pediatrics, entitled Lessons from Drugs to Devices: A Pediatric Perspective. We noted that “the testing and approval of high-risk medical devices in children younger than 18 years remain extremely uncommon.” In 2019, this observation still remains true. We know that incentives in the form of legislation and availability of grant programs have greatly facilitated the development of orphan drugs. Although there are inherent differences in drug and device development pathways, there are helpful lessons to be learned from the drug world. Additional incentives for device innovators would help to reverse the current lagging trend of pediatric device approvals in comparison to drug and biologics approvals.

NCC-PDI’s long-term goal is to contribute to the national effort to close the gap to bring more pediatric devices to market. Our short-term and operational goals are to continuously enhance our capabilities in providing expert advising and support services to innovators of pediatric medical devices, focusing on the total product life cycle for medical devices from concept, through pre-market development, to commercialization, and replacement by subsequent generation of devices. NCC-PDI’s 6-year report card (ending in August 2019) shows that the 104 device projects that came through our accelerator program were able to raise $148,680,256 in follow-on funding and 5 medical devices were cleared to market either by the FDA or through CE mark of approval.

Wearable Biosensors in Pediatric Cardiovascular Disease: Promises and Pitfalls – Frame of Reference Perspective

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Introduction

Wearable biosensors gather continuous physiologic data (CPD) in real-time, generating information reflecting the patient's current real life state. The paradigm of using CPD to guide clinical decisions is expected to be a major advance for patients with chronic diseases like congenital heart disease (CHD), and form part of the evolution from episodic to continuous patient care. In adult cardiovascular populations, there is already growing evidence of the benefit of mobile health (mHealth) technologies. However, most mHealth technologies, especially wearable biosensors, are not designed for children, despite numerous specific pathologies that could benefit from this technology. This article will summarize some of the opportunities and challenges for the use of wearable biosensors for cardiovascular health in children, which are presented in more depth in our recent publication.¹

Clinically Actionable Insights

One key driver for the development of wearable biosensors is the potential to use CPD to generate real-time, clinically actionable insights from predictive analytics that include early warnings of clinical deterioration and prompts for behavioral changes. The advent of machine learning methods that can detect subtle patterns from large sets of CPD may make this achievable.

Where might CPD have a role in pediatric cardiology? Patients with single ventricle heart disease who are between the first and second stages of surgical palliation (the “interstage” period) have high morbidity (e.g. unplanned readmissions and catheter interventions) and mortality. In the ICU setting, retrospective analysis of EKG tracings predicted cardiopulmonary arrest in this population.² Interstage patients’ high morbidity and mortality continues after discharge, so perhaps wearable CPD and predictive analytics could be used to predict these events at home. Malignant arrhythmias in high-risk populations like CHD and long QT syndrome present additional targets for continuous monitoring with wearables. Even longer-term deterioration detection for patients with heart failure, through monitoring tachypnea, tachycardia, weight gain, and thoracic impedance may be amenable to detection with wearables in children like it is in adults.

Cardiometabolic Risk Factors

Given the high rates of obesity and cardiometabolic risk factors in children, another key potential use for wearables is early intervention to prevent atherosclerotic cardiovascular disease in adulthood. Here, the focus so far has been on step counters to encourage physical activity. Systematic reviews suggest mHealth interventions have a small but significant effect to increase physical activity, and may improve dietary intake.³ Of course there is no guarantee that wearables improve outcomes: a large randomized trial in adults showed that a wearable device in addition to weight counseling actually led to decreased weight loss.⁴ More data are needed to see if wearables have a beneficial impact on downstream risk factors in youth.

Physiologic Parameters

A fundamental challenge in designing wearable biosensors for pediatric cardiovascular applications is that physiologic parameters have a very broad range in childhood, including normal heart rates and expected oxygen saturations. To be optimized for pediatric populations, biosensors will have to be designed with these extreme physiologic states in mind, affecting battery life, sampling rates, and how quality control is performed. Recent data show that leading consumer wearable pulse oximeters have suboptimal accuracy, leaving considerable room for improvement.⁵

High-Risk Populations

Choosing appropriate pediatric populations will be key for yielding clinically-useful insights. In particular, generally healthy children very rarely have unpredictable, catastrophic events.⁶ This means that sensitive markers of decompensation will

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have low positive predictive values in the face of low prevalence. Therefore, using wearable CPD to generate predictive analytics for healthy children is likely to yield more false positive than true positive alerts, and we should focus on high-risk populations. The American Academy of Pediatrics currently recommends against the use of home monitors for SUID prevention.\(^7\)

**Wearability/Form Factors**

The usability, or “wearability,” of these devices in children has been minimally evaluated; even for adults, there is limited literature. A wearability assessment should include device-specific parameters including accuracy and battery life, but also false positive and negative alerts, cost, data security, and comfort. Compliance with devices is likely determined by a combination of patient and parental wearability factors. Small studies show that factors like comfort, fit, body location, and features like waterproofing affected compliance for activity monitors in children;\(^8\) it is likely that more complex wearables will have more complex compliance parameters. As in adults, compliance waned the longer the studies ran, but perhaps parental intervention would increase compliance in infants and young children. Wearable device form factors must account for smaller size, developmental factors, and expected somatic growth in children.

**Market Factors**

Due to the widely varying physiology and form factors required, biosensors may need to be designed specifically for children and those with congenital heart disease, or at least adapted for use. To that end, with smaller populations of sick patients, pediatrics is often not a key market for industry. Thus, the FDA P50 Pediatric Device Consortia serve as an invaluable resource to encourage development. In addition, it is up to us as a field to be creative and help guide industry to beneficial use cases or areas where a pediatric and adult problem may be solved simultaneously, thus providing a new market “for free.”

**Psychosocial Factors**

There are psychosocial and developmental aspects that need to be considered. Device design should allow pediatric patients to act and feel like kids, not patients under constant surveillance, and allow normal family dynamics. Parents and caregivers of children with chronic illnesses often show signs of increased stress, so wearability should also target their quality of life as well.\(^9\) Interestingly, the use of insulin pumps reduces both patient and caregiver anxiety, partly due to decreased fear of hypoglycemia;\(^10\) perhaps validated wearables may do the same for high-risk CHD populations.

**Sources of Optimism**

Fortunately, wearable biosensor technology is rapidly developing and addressing some of these challenges. No single type of CPD will likely be sensitive or specific enough to generate actionable insights, so combination sensors might be useful. Sensors that target novel physiologic signals are being developed, e.g. seismocardiography and phonocardiography to measure chest vibration, and sweat and microneedle sensors for metabolites. Finally, analytical techniques are overcoming limitations of machine learning by, for example, reducing the dataset size needed for training.

These developments provide an opportunity to fundamentally shift our interactions with patients from episodic, hospital and clinic-based to more continuous, home-based care. However, clinicians need to creatively engage industry to make wearables that address pediatric needs and are appropriate for individuals with CHD. We should continue to evaluate the accuracy and validity of biosensor readings, and be open to testing novel biosensors that may provide new physiologic insights. Successfully integrating continuous monitoring into pediatric cardiovascular care will require collaboration between clinicians, industry, and regulatory bodies, and we are optimistic that these challenges can be solved.

If physicians, families, or industry partners are interested in discussing any of the above, including testing devices, thoughts about wearability, etc., please contact me!

**Sources of Funding**

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the Pogue Family Foundation Master Clinician in Pediatric Cardiology via Dr. Thomas Zellers. The content is solely the responsibility of the authors and does not necessarily represent the official views of any of the funding agencies.

**Conflict of Interest Disclosures**

Dr. Tandon receives significant research grant support from Synergen Technology Labs.

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**Predictive Analytics Derivation**

![Diagram](image)

**Predictive Analytics Implementation**

**Figure 1.** Diagrammatic representation of predictive analytics. The wearable biosensor collects continuous physiologic data and eventually transmits it to the cloud. Adverse events are collected and correlations are determined between CPD patterns and events using machine learning. Then, real-time pattern detection can be implemented in the cloud to generate alerts based on CPD analysis, and transmitted to the patient, family, and medical team.

**References:**


*Continued on Page 10*
Virtual reality (VR) is a rapidly growing form of therapy in children's hospitals. Children don a head mounted display that depicts a simulated, interactive, 3D environment. Visual graphics with spatial orientation, combined with binaural audio and haptic feedback on handheld controllers create a completely immersive experience. VR for children has implications beyond merely entertainment. It is an emerging modality to bring joy and distraction, plus promise to reduce pain and anxiety in pediatric patients.

Most of the literature for use of VR in children to date targets reducing pain or anxiety with needle-based procedures. A number of studies demonstrate that VR given to children during venipuncture, vascular access, or immunization successfully reduces fear, pain, or anxiety.1-7 One study found no reduction in pain with use of VR for venipuncture.8 There is some theory that directing a child's cognitive load towards a task (such as a VR game) takes the focus off of the IV and thereby creates a better experience.9

Children with burns who require repeated dressing changes or physical and occupational therapy are subject to much discomfort. Research of VR for this population, however, shows mixed results. Several studies show that VR significantly reduces pain, compared to analgesia alone.10-14 Another study found no significant reduction in pain for burn wound care.15

Psychologists have found VR an optimal environment to coach patients on tackling phobias and anxiety. VR permits for reproducible, controlled, and safe environments for patients to address their fears of heights, spiders, or crowds.16-20
Patients can practice overcoming obsessive, compulsive thoughts or aversions in a virtual environment. In other modules, biofeedback is gamified through different challenges that require control of their breath and heartbeat.  

Other novel implications for VR in children include training to tolerate a MRI scan or day surgery preparation. The virtual environment can prepare a child with what they will see and hear in a MRI scanner, theoretically improving odds that the child will tolerate the scan without sedation. VR has a role in reducing pain outside of procedures. VR has been studied as an adjunct to pain medication in a sickle cell population with vaso-occlusive crisis.

Virtual reality is a novel adjunct to current therapeutic modalities to help children cope with their medical care. However, VR is not a one-size-fits-all solution. The body of literature on VR in pediatrics remains in its infancy. The evidence thus far supports use of VR for some settings and some patients, but is equivocal for others. Ongoing research will reveal the optimal indications for VR in a children's hospital. Another major limitation with VR is the size of the head-mounted display. Current commercial headsets suggest a lower age of 13 years. Researchers have published data on its use in children as low as age 7. The main limitation in age stems from the interpupillary distance of the binocular eyepieces, the size of the headset, and also developmental maturity of the child to verbalize what they are experiencing. One center created a custom headset that accommodates children ages 4-11; this is the youngest age group studied with use of VR. Finally, few VR games are designed with a pediatric procedure in mind. VR games optimal for a clinical procedure must limit head or hand movement, have age-appropriate content, and not provoke anxiety (e.g. roller coaster rides, war games). One developer (KindVR) creates games expressly for a pediatric patient and meet these criteria, though they are unique in this space.

The future of virtual reality continues to evolve. Each iteration of the technology has improved display resolution, advanced degrees of freedom of movement detected in the virtual world, and faster processing power. Developers are creating more applications that are tailored to the care of the ill or injured child. The technology isn't moving fast enough, however. There remains a gap in commercially available VR for the pre-school aged child and for games that are procedure-friendly. As the VR technology evolves, children's hospitals should adapt with it. Child life specialists are an ideal group to support and champion a virtual reality program at local institutions. Child life specialists might use VR in their armamentarium to help children cope with their procedures or pain. Research and accompanying protocols are still needed to assist others who want to integrate VR into their space. Despite the unknown, the previous literature generally reports few and infrequent side effects related to motion sickness. With a low cost-point (many off-the-shelf headsets are < $300), low risks to the patient, and potential to reduce pain or anxiety, virtual reality may be a strategy worth employing across more pediatric settings.

References


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**Have You Visited SOATT’s New Web Page?**

[https://collaborate.aap.org/SOATT](https://collaborate.aap.org/SOATT)

Only basic information about SOATT is on AAP.ORG  
[https://www.aap.org/SOATT](https://www.aap.org/SOATT)

All of the members only documents are on the collaboration page. Check it out!
Pediatric Medical Device Spotlight

LifeBubble™ Umbilical Catheter Protection and Stabilization Device

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Email: eric@novonate.com

Novonate Inc. proudly announces LifeBubble™ for use in the neonatal intensive care unit. This device streamlines the process of umbilical catheter stabilization and protection in neonates.

Umbilical catheters are lifelines in the neonatal intensive care unit (NICU). They are a painless and relatively quick way to gain central vascular access, facilitating the infusion of vital medications and nutrition, blood draws, and invasive blood pressure monitoring. However, these catheters are not without their risks. Complications associated with umbilical catheters include pericardial effusion, hepatic vein thrombosis and bloodstream infections, which researchers have associated with migration of the catheters.\(^1\)\(^2\)\(^3\) Furthermore, recent studies have found that up to two-thirds of umbilical venous catheters migrate after initial placement.\(^4\)\(^5\) For central line associated bloodstream infections alone, this complication costs NICUs up to $90K in additional cost and 31 days of longer length of stay.\(^6\)

Umbilical catheters are the only central lines without barrier protection at the site of insertion and are externally secured with nothing more than reconfigured adhesives (Figure 1). Occlusive site dressings that provide sterile barrier protection and are standard in the care of adult and pediatric central lines cannot be used for umbilical catheters as the line is inserted through the umbilical stump that must be allowed to naturally desiccate.\(^7\) Sterile barrier protection of the insertion site guards against potential sources of infection, such as bacteria on the hands of caretakers or from the diaper. Another challenge is allowing for independent securement of one or more catheters. Currently, if an umbilical catheter needs to be repositioned or removed, securement is temporarily removed from all umbilical lines, potentially compromising the positioning of a second catheter and requiring the reconstruction of another adhesive-based securement. Furthermore, the process of looping a catheter into an adhesive is not a standardized procedure, thereby resulting in varying levels of securement based upon styles of anchoring.

The NICU has a clear unmet clinical need for a securement and protection device that is specially designed to keep these umbilical lifelines in place and protect one of the most important components of neonatal care.

Figure 1. The two most common ways of securing umbilical catheters using adhesives.

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1 Sulemanji M. Neonatology 2017, 111:337-343.
7 The Joint Commission, 2013.

Continued on Page 14
LifeBubble is a sterile silicone device providing unparalleled catheter protection and stabilization.

LifeBubble was developed by neonatologists, surgeons, and engineers from Stanford University with ongoing design input from NICU nurses to revolutionize the way umbilical catheters are held in place given the complications that can arise from these necessary but exposed central lines.

LifeBubble standardizes the way that catheters are secured by simplifying the process for care providers. After the line has been inserted, LifeBubble can be immediately used since it is a sterile device; it can also be used by bedside nurses as a part of standard line care.

Figure 2. LifeBubble securing an umbilical cord catheter while protecting the insertion site.

LifeBubble sits over and around the insertion site providing a sterile barrier that protects the catheters from movement and external contact (Figure 2). It has ventilation slots that enable natural stump desiccation. LifeBubble is adhered to hydrocolloid adhesives to protect skin. Catheters are then wrapped around LifeBubble's securement knobs and secured by pulling an elastic strap over the top of each securement knob (Figure 3). LifeBubble is easily removed or replaced, which facilitates adjustment of one catheter (eg, removal of the umbilical arterial catheter) without the need to remove adhesives or perturb the second line (an umbilical venous catheter). In addition, nurses can easily visually assess the insertion site through a fully transparent window at the top or through the vents. The mechanical method of securement means that the catheters are still reliably secured under heat and humidity, which is in contrast to the fully adhesive-based methods of securement that are at risk of degradation or melting over time.

Continued on Page 15

**We Need You!**

**How to Join . . .**

It's easy! There are NO DUES to join the SOATT if you are an AAP member.

Send an e-mail to Jackie Burke at [jburke@aap.org](mailto:jburke@aap.org) to request to be added to the Section.
LifeBubble™ Umbilical Catheter Protection and Stabilization Device  Continued from Page 14

Figure 3. LifeBubble: Instructions for the simple securement of umbilical catheters

LifeBubble is currently being used in several NICUs and has received widespread praise by the NICU nurses who use it! Over 90% of LifeBubble users believe that the device is secure, protective, quick to apply, and easy to use. Many nurses have noted that the improved and more elegant method of securement have led them to feel more comfortable with line care and securement; one NICU nurse said "I love that LifeBubble secures catheters so well. We, as nurses, are typically so wary of umbilical lines in the first couple of days. But with LifeBubble adding a level of securement, I’m definitely more comfortable with [...] the overall care of the baby!" One neonatologist also said that “it’s crazy that we got used to just using tape on these catheters. LifeBubble is so much more elegant and keeps everything protected and secure.”

LifeBubble is commercially available in the United States. Contact the Novonate team at info@novonate.com to bring LifeBubble to your NICU!

ABOUT NOVONATE

Novonate Inc., is a medical device company dedicated to designing products aimed towards the care of neonates. LifeBubble is the primary device developed by Novonate that protects and stabilizes the umbilical catheter in neonates and standardizes the process of stabilization for healthcare providers. The company is based in South San Francisco, California. For more information, visit www.novonate.com.
The website for the American Board of Pediatrics states, “MOC (Maintenance of Certification) assures pediatric patients and their families that ABP-certified pediatricians are actively working to stay up to date with the most current medical knowledge over the course of time that they practice medicine.” In my opinion, the American Board of Pediatrics could modify the Maintenance of Certification program without compromising this assurance. Specifically, the Board should allow alternative strategies for participants to receive credit for improving care processes and care outcomes.

The current MOC process requires diplomats to:
- Part 1 Demonstrates professionalism
- Part 2 Engages in life-long learning
- Part 3 Pass periodic medical knowledge assessments
- Part 4 Participate in quality improvement activities

I believe Part 1, Part 2 and Part 3 are reasonable expectations. Patients and families should expect their pediatrician to be a professional, be up to date with current care practices and be able to pass periodic examinations related to their specialty or subspecialty. However, there is no evidence that pediatricians who participate in quality improvement activities are better care providers than those who strive to improve care processes or care outcomes in other ways.

The President of the American Board of Pediatrics, David Nichols, has defended the MOC process. He has stated, “The certifying boards have targeted Quality Improvement as the primary vehicle for a catalytic effect on care, in part because of the urgent appeals from the National Academy of Medicine that the health care system make QI and patient safety a priority. A catalyst enables a process to occur that may not have the impetus to occur spontaneously or with reasonable effort. Quality improvement projects do not facilitate a meaningful effect on care for individuals who are already improving processes or outcomes in other ways. In a sense, the requirement to perform quality improvement activities simply becomes a distraction from efforts of equal or greater value.

The required quality improvement activities for MOC Part 4 may fail to improve quality or safety. In order to improve quality, participants must repeatedly plan, do, study and act (PDSA). Many of the quality improvement activities that satisfy requirements for MOC Part 4 are short-term and only cover the span of one PDSA cycle. Further, a key element of quality improvement is performing a task the same way, even if it is the wrong way. This process has been employed by large automobile manufacturers to improve their products over time. Arguably, the process has been effective. However, there have been dangerous consequences resulting in large recalls of automobiles. Similarly, some quality improvement efforts in medicine could be associated with substantial risks. However, IRB approval is not required for care providers to perform quality improvement studies in many institutions. The analysis of quality can also be complex. For example, a large quality improvement collaborative might observe trends to support the efficacy of specific interventions and later learn the results were primarily influenced by the outcomes of a few centers, not the interventions. In my opinion, the American Board of Pediatrics has placed too much emphasis on, and has overstated the impact of, a single method to improve care processes and care outcomes.

We can foster the quality of care through medical research, education, advocacy and innovation; instead of doing something the same way even if it is the wrong way. Those who think outside the box are able to perceive alternative strategies and solve complex health care problems. Our talented colleagues in research, education, advocacy and innovation should be rewarded, not coerced to perform quality improvement activities simply for the sake of meeting an arbitrary standard.

I offer a few examples of valuable alternative efforts that compliment quality improvement activities and should similarly satisfy requirements for MOC Part 4.
- Perform and publish a basic, translational or clinical research project that may improve care.
- Publish a case report that describes a process or technique that may improve care.
- Collaborate with a sponsor in industry and participate in a clinical trial.
- Participate in a multi-center registry for a rare disease.
- Develop a medical device that is designed to improve care.
- Develop a method or process for improving the diagnosis of disease.
- Develop teaching strategies to improve the education of pediatric care providers, patients or families
- Advocate for the care and protection of children in a political setting.

Clearly, quality improvement activities are not the only, or consistently the best, activities to improve care. I hope the American Board of Pediatrics will expand the options of activities in MOC Part 4 and reward all pediatricians and pediatric subspecialists who are striving to improve the care and safety of their patients.

Reference


The Process for Advancing the California Neonatologists and Newborn Intensive Care Unit (NICU) Directory from a Paper/ PDF Format into Web directory and Readiness for Review and Implementation

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AAP Section on Neonatal and Perinatal Medicine (SONPM) Chair of Task Force for Neonatal Perinatal Therapeutic Development, and Liaison to SOATT
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*Kimber Padua, BS*
Stanford University School of Medicine

The objective for this article is provide a sequel to the SOATT Newsletter publication “A Perinatal-Neonatal Clinical Trials Regulatory Research Directory Can Facilitate Establishing a Neonatal Perinatal Research Network” Spring 2018 (also see J. of Perinatology 15 March 2018; https://doi.org/10.1038/s41372-018-0097-8; Section on Neonatal and Perinatal Medicine Newsletter Summer 2018, p.12, https://www.aap.org/en-us/Documents/Perinatal-Newsletter.pdf) and to introduce the launch of the 2019 Neonatal Intensive Care Units and Neonatologists in California Web Directory.

**Chronology for this Project, initiation and funding:**
In the last 18 months, we have obtained the approval of our proposal and consensus from the California Association of Neonatologists (CAN) to initiate the Web Based Directory project. Of interest, the CAN Board includes elected representation from AAP District IX, Section on Neonatal Perinatal Medicine (SONPM). Seed funding was generously provided from Dr. David Stevenson, Chief of the Division of Neonatal and Developmental Medicine at Stanford and from CAN. We also have a grant from Mead Johnson Nutrition (original funders of Directory project in 1994 through 2011). Dr. Dilip Bhatt, with the assistance of Dr. Marian Adams and Janice Stillwell, were dedicated and labored tirelessly to obtain the data for California. We are pleased to have a contract with Fibonacci Web Studio (https://fibonacciwebstudio.com/) and the leadership of Ms. Irina Zaks for the development of the Web Directory. Ms. Zaks has successfully collaborated with Dr. Bhatt and Ms. Stillwell to transfer PDF data into a Web platform. The leadership of my colleague, Dr. Henry Lee and the California Perinatal Quality Care Collaboratives (CPQCC), and Ms. Kimber Lee Padua, Clinical Research Coordinator

*Continued on Page 18*
(CPQCC) and Dr. Meera Sankar, Chair of CAN Research Committee have been essential. In a word, the leadership from CAN and CPQCC and the potential to link to existing CA NICU database have been key to facilitating this project.

Technical Details on Development

The NICU Directory website was developed using the Pantheon platform (https://pantheon.io/company) linked to the California Perinatal Quality Care Collaborative (CPQCC) website. Pantheon is a “webops platform” for Drupal, which allows for a high-performance hosting platform. Drupal (https://www.drupal.org/) is a free open-source content management framework, which supports the concept that CPQCC and NICU teams endorse collaboration and innovation. Pantheon and Drupal were primarily chosen because they are user friendly, have capability to download new data, easy to navigate and share data with others when permitted.

The NICU directory data accumulated from April 2019 was reviewed. Each center was listed by California city with the address, phone number, fax number, NICU medical director and email. Additional important information about the NICU included each center's level of practice, number of NICU beds, availability of hypothermia treatment for hypoxic ischemic encephalopathy (HIE), and use of inhaled nitric oxide (iNO). The clinicians listed under each center included Neonatologists, Neonatal Nurse Practitioners (NNP), Neonatal Physician Assistants (PA), Perinatologists (Maternal Fetal Medicine specialists), Hospitalists and Pediatric Surgeons if relevant.

After each center was updated and the data was verified for accuracy by Drs. Bhatt and Adams, they were input into the online platform. In the Web Directory there are tabs for Centers, NICU Medical Directors and People Directory. The Centers' tab is categorized by Training Centers, CCS Approved NICUs, Non-CCS (California Children's Services) NICUs, and Clinic and other facilities. The NICU Medical Directors page shows a list of Medical Directors matched with their respective NICUs. The Medical Director name is a hyperlink that links to their personal page within the directory. The NICU is a hyperlink that links to that center's page. The People Directory is organized alphabetically by first name, and has an available search bar to look up providers, with hyperlinks to each of their personal pages within the directory. There is also a separate tab for User Guide, for members to refer to the basic steps of managing their profiles or centers, as well as a Feedback tab for members to offer input to improve the website.

Testing, Pathway to Consensus, Approval and Implementation:

Six NICU Medical Directors from training programs agreed to test the website and provide feedback on the overall ease of use and navigating through the different tabs. One of the takeaways was a concern about how much information should be made public. There were concerns about whether the number of hospital beds and use of iNO should be made public. On the other hand, the argument was made that some pediatricians and/or Maternal Fetal Medicine providers should be able to see that information in order to appropriately refer patients to the right NICU. Another takeaway was the need to establish appropriate restrictions on what can be viewed in the directory. Specifically, a fellow may be looking for a job, but if they are not a CAN member they do not have login access. How to approve and provide the appropriate level of access will need to be addressed. The next beta testing of the NICU directory website will take place in early October 2019. We will present these results to CAN Board for review, and consideration for approval and launch of the California Neonatologists and Newborn Intensive Care Unit (NICU) Directory.

Next Steps and Goals:

Following the timeline for the original 1994 CA Neonatology Directory we plan to present to SONPN Executive Committee for review and to propose and ask support to extend this project to a National Web Directory (the original chronology was in 1996). An interim project, which is under discussion with SONPM leadership, would be to update the Organization of Neonatal Perinatal Training Program Directors (ONTPD) data and transform into a Web Directory. Of interest, we previously published that this Directory was informally updated post 2011; however, newer information is that minimal contact data was all that is currently available.

Development of a Clinical Regulatory Research Web Directory:

As previously detailed in J. of Perinatology 15 March 2018; https://doi.org/10.1038/s41372-018-0097-8 a very important goal for the field of Neonatal Perinatal Medicine is to establish a Clinical Trial Regulatory Research Directory, which we recommended to be done in collaboration with the NICHD Pediatric Trials Network (PTN) leaders.

Continued on Page 19
NICUs, which are reviewed and approved for regulatory trials, must adhere to higher bar for scientific rigor compared to what is usually considered adequate for routine clinical trials. Data collection must be done under 21 CFR Part 11 compliant conditions, which requires training and use of specific types of electronic data capture platforms. Sites must also be prepared to undergo audits from sponsors, research organizations, and the FDA. It will be important to have the expertise of the PTN leadership to help CA identify the NICU centers, which are qualified and address how to obtain the resources needed for NICU centers who need help to participate. In CA there are 10 Training Center NICUs, each of which has many affiliate NICUs, that could be incorporated into a research network under the guidance and support of the Training Centers. Inclusion of affiliate NICUs would maximize participation of virtually all NICUs in CA. We could optimize neonatologist (400 plus) and Neonatal Nurse Practitioner and neonatal nurse workforce and augment the infant population available for participation. Currently, there are ~138 NICUs in CPQCC data base, which represent 95% of very low birth weight infants for trials.

A regulatory clinical trials research directory would give appropriate and approved stakeholders access to qualified individual sites. A search function could identify sites that have the capacity to engage participants in multiple settings (e.g., NICU, outpatient clinics) and site experience conducting various types of trials. Sites would document access to appropriate research equipment (e.g., freezers, dry ice, and centrifuges) and ability to use electronic health databases to identify participants. Pharmacy capabilities could be assessed (e.g., blinding, investigational drug pharmacies, weekend/night coverage). Investigators would be able to explain IRB requirements (e.g., use of central IRB vs. local), typical time to put contracts in place, and whether they had previously undergone audits by sponsors or the FDA.

When the CA Clinical Regulatory Trials Web Directory is established we would welcome becoming the test case to evaluate the utility of the platform to organize and to conduct a network regulatory clinical trial.

**Development of Global NICU and Neonatologist Web Directory:**

Continuing the alignment with the history of the original directories, “Newborn Intensive Care Units (NICUs) and Neonatologists of the USA and Canada Directory 2011”, we would begin the extension of the National Directory to include Canada. Perhaps, with the assistance of Canada iNeO Research Network (http://www.ineonetwork.org/), the Directory could initiate the international/global extension. At this juncture in development, collaboration with existing national and global data bases such as VON (Vermont Oxford Network) will be important to allow for the possibility of essential links to enhance the Web Directory.

**Conclusion:**

We hope that this Neonatology Web Directory project may be a model for establishing a Global Pediatric Clinical Regulatory Research Web Based Network, which is being organized by the Institute for Advanced Clinical Trials for Children (https://www.iactc.org/) and for the International Neonatal Consortium (INC, https://c-path.org/programs/inc/) to enhance their national and global mission.

For the Web Directory(ies) to be successful: 1. we will need the consensus for ownership and involvement of all neonatologists and clinical programs, who will be committed to take an active role in updating online; 2. Neonatologists will need to provide insightful input on how to expand the data in the directory; 3. Include the capability and flexibility to add new information/links to increase the impact/utility of the Directory, e.g., include information on all subspecialists who make highest level of intensive care feasible; 4. Establish a plan for sustainability: such as administration and funding, which in part will include membership fee. 5. Achieve agreement on what information will be essential for training, research and clinical practice with the ultimate goal to improve clinical care and outcomes for mothers and infants.
As the seasons change into the brisk days and even cooler evenings, the International Children's Advisory Network (iCAN) continues into our 5th year as the premier organization that supports pediatric and adolescent medicine through science, research, technology, innovation and advocacy. As we finish out the year, we continue to be busy with a multitude of projects emphasizing patient engagement through sharing the expert voices of our youth members and their families. iCAN knows that the ability to create positive change that meaningfully improves outcomes in pediatric healthcare is through creating a platform in which kids can share their expert voices.

As many of you know through your attendance and support, the annual iCAN Summit was held in Kansas City from June 24th-June 28th, 2019 at the Westin Crown Center. iCAN, along with KIDS Kansas City, led by chapter leaders Amanda Woelk and Melissa Pulis, hosted an international roster of medical professionals from hospitals, industry, pharma, and non-profit sectors. This year’s agenda includes speakers from around the world, including an outstanding presentation from our American Academy of Pediatrics (AAP), Dr. Susan Walley, MD, Chair of Pediatrics Section on Tobacco Control. Dr. Walley’s discussion included an interactive dialogue where attendees could ask questions and share their experiences with vaping and e-cigarettes. Concluding her presentation, youth members became knowledgeable ambassadors that were able to speak effectively and clearly about the dangers of using nicotine products.

Also in June, iCAN partnered with the Food and Drug Agency (FDA) to represent youth patient perspectives in a panel discussion highlighting the efforts of KIDS Chapters to work collaboratively, nationally, and globally to better understand quality improvements and to increase patient-centered research, innovation, and advocacy. This outreach event kick-started another event to be held later this month, in which seven youth members from chapters around the United States will attend a second meeting focused on understanding pediatric patient needs.

iCAN also released a new web-based portal for youth members and families to visit with open projects and opportunities. This interactive page offers activities for youth members to drive positive change through travel, surveys, speaking and writing events. To visit the page and learn more: https://www.icanresearch.org/open-projects

Please save the date for July 13-17, 2020 as we begin planning the 6th Annual International Research and Advocacy Summit to be held in Lyon, France in partnership with KIDS France. iCAN is currently accepting speakers and sponsors.

If you are at the AAP NCE 2019 this month, please stop by and say hello at our iCAN booth. We hope to see you there!
Dear Section on Advances in Therapeutics and Technology (SOATT) Members –

You probably know that registration and housing is open for AAP National Conference October 25-29 in New Orleans. Your Section (SOATT) has some programs going on during this meeting. Please keep these in mind as you’re making travel arrangements:

**SATURDAY, OCTOBER 26, 2019**

**F2206 Revolutionizing Pediatric Care With Health Technology**

- **Session Type:** Focused Topic
- **Topic(s):** Advances in Therapeutics & Technology

Faculty will share ground-breaking health technologies from the past five years that hold the most promise to bring the greatest good for child health globally.

**Faculty**

Vasum Peiris, MD, MPH, FACC, FASE, FAAP
Chief Medical Officer - Pediatrics and Special Populations
U.S. FDA Center for Devices and Radiological Health
Silver Spring

**Monday, October 28**

2-3:30 PM
Ernest N Morial Convention Center 388-390

2:00 PM  **Welcome & Introduction**  
*Edress Darsey, PharmD, FPPAG* and *Mitchell Goldstein, MD* (Section Chair)

2:05 PM  **Presentation of Section Achievement Award for Pediatric Innovation**  
Recipient: Wilbur Lam, MD

2:15 PM  **Section Awardee Keynote Address**

2:45 PM  **Research Paper Poster Walk & Section Reception**

3:20 PM  **Section Awards for Top Three Research Paper Presentations**  
Moderator: *Edress Darsey, PharmD, FPPAG*

3:30 PM  **Adjourn**
A Message from the Membership Committee

Chris Rizzo, MD, FAAP
SOATT Membership Committee Chair
crizzo624@gmail.com

It is an exciting time to be involved in generating new information on pediatric technology, devices and medications.

Those of you reading this newsletter are likely SOATT members. We rely on your help to recruit others to the Section. Members of the Section do not need to be eligible for AAP membership. See below for membership categories and eligibility.

Our Section continues to grow and now has 965 members!

Who Can Join?

1. AAP Members

Membership in the section is open to AAP Fellows, Specialty Fellows, Candidate Members, Post Residency Training Members, Honorary Fellows, Emeritus Fellows, and Corresponding Fellows with an interest in advances in therapeutics and technology. There is no fee for AAP members.

2. SOATT Affiliate Members

Affiliates are those who are not eligible for membership in the AAP and hold a Masters degree or Doctorate (or equivalent) in pharmacy or other health science concentration. Affiliates must submit an application (see “How to Join” below) and have a signed letter of support from an AAP fellow in good standing. There is a $40 annual fee for section affiliate members.

How To Join?
If you are already a member of the AAP and would like to become a SOATT member, join online by:

1. Going to Member Center of the AAP website and use your AAP login and password.
2. Click on “Join a Section or Council” under Member Community
3. Choose “Advances in Therapeutics and Technology”, answer a few questions, and click “Submit”.

Membership applications can be found at:
Members:  http://membership.aap.org/Application/AddSectionChapterCouncil
Affiliates:  https://membership.aap.org/Application/SectionAffiliate

If you have any questions about membership, please contact Chris Rizzo MD, FAAP at crizzo624@gmail.com or the section staff at jburke@aap.org.
<table>
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<th>Welcome New Members</th>
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<th>Sajjad Yacoob, MD</th>
<th>Yashvantkumar Patel, MD, FAAP</th>
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<tr>
<td>Jonathan Routh, MD, MPH</td>
<td>Stefan Iorga, MD, FAAP</td>
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<td>Hevil Shah, MD, MPH, MA, FAAP</td>
<td>Peter Grubb, MD, FAAP</td>
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<td>Hunaid Gurji, DO, PhD</td>
<td>Stuart Copeland, MD, FAAP</td>
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<td>Mohammad Adnan, MBBS, FAAP</td>
<td>Marissa deUngria, MD, FAAP</td>
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<td>Agnes Asiedu, MD</td>
<td>Gianina Davila, MD, FAAP</td>
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<td>Kunal Kaushik, MBBS, FAAP</td>
<td>Rebecca Rose, MD, FAAP</td>
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<td>Mariana Boscan, MD</td>
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<td>Frederick Lueder, MD, FAAP</td>
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<td>David Whiteman, MD, FACMG, FAAP</td>
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<td>Lawrence Sweet, MD, FAAP</td>
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<td>Cindy Calderon, MD, FAAP</td>
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<td>John Erickson, MD, FAAP</td>
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<td>Rachelle Wells, CPNP-PC</td>
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<td>Casandra Grimmett, FNP-C</td>
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<td>Melissa Montopoli, FNP-C</td>
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Announcements from the AAP

Open SOATT Leadership Positions

The AAP Section on Advances in Therapeutics and Technology (SOATT) has two openings for leadership positions. (3-year term renewable once, positions begins November 1, 2020.)

If you are a member of the AAP and the SOATT and are interested in a position, please submit your 250-word bio-sketch to jburke@aap.org no later than December 31, 2019.

Leadership responsibilities include:

- Reviews all relevant material before meetings. Makes contributions and voices objective opinions on issues.
- Attends all meetings and conference calls (1 face to face meeting in October each year = travel paid by AAP) (conference calls, 1 hour each quarterly).
- Take the lead in section activities appropriate to expertise and to serve on a subcommittee as necessary.
- Carries out individual assignments made by the chairperson and/or staff.
- Represents the section in meetings of other sections, committees, or organizations as directed by the Academy.
- Serves as spokesperson on behalf of the Academy to the media, outside organizations, and others as requested by the Academy.
- Discloses potential conflicts of interest.

If you have questions about the positions, please contact Jackie Burke at jburke@aap.org

Thank you!

Section Produces Patient Education Brochure on Clinical Trials

Should My Child Join a Clinical Trial? Patient education brochure was updated and published in March 2019. The brochure covers:

- Why are clinical trials for children needed?
- How are clinical trials done?
- What are the benefits and risks of a clinical trial?
- What do I need to know before I sign up my child for a clinical trial?
- What questions should I ask about a clinical trial?
- Words to Know
- For more information

For a free sample copy of the brochure, please contact AAP Customer Services at 866/843 -2271.

SOATT Leadership Team

Mitchell Goldstein, MD, FAAP  
*Chairperson, Executive Committee*

Ron Ariagno, MD, FAAP  
*Co-chair, Research Subcommittee*

Francis Dick-Wai Chan, MD, FAAP  
*Liaison to Council on Clinical Information Technology*

Susan Cummins, MD, MPH, FAAP  
*Member, Executive Committee*  
*Co-chair, Research Subcommittee*

Karen Kaplan, MD, FAAP  
*Member, Executive Committee*

Chester J. Koh, MD, FACS, FAAP  
*Newsletter Editor*

Robert Leggiadro, MD, FAAP  
*Member, Executive Committee*

Holly Lindsay, MS, MD, FAAP  
*Liaison to Section on Early Career Physicians*

Christina Bucci-Rechtweg, MD, FAAP  
*Chairperson, Educational Program*

Mark Puder, MD, FAAP  
*Member, Executive Committee*

Chris Rizzo, MD, FAAP  
*Chair, Membership and Communication Subcommittee, Chairperson - Elect*

Charlie Thompson, MD, FAAP  
*Immediate Past Chairperson*

Robert Walker, MD, FAAP  
*Member, Executive Committee*

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